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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,681	02/01/2001	Linda A. Sherman	313332000101	3045

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	09/774,681	SHERMAN ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 6-34 is/are pending in the application.

4a) Of the above claim(s) 6,18-21,30,31 and 34 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 7-17,22-29,32,33 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election of the species construct of claim 32 in the reply filed on 12/6/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 6,30,31 and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/6/06.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The previously pending rejections of claims 6,9-12,15-19,22-30 as rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement are withdrawn in view of the amended claims and because claim 6 has been withdrawn from consideration.

5. Claims 7-17,22-29,32,33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a)There is no support in the specification as originally filed for the recitation in claim 32 of "further comprising a polypeptide spacer between the TCR variable domain and the transmembrane and cytoplasmic region of a CD3, CD8, or CD16 receptor". Regarding applicants comments about the specification, page 6, lines 10-14, said passage discloses a particular construct in Figure 1, that uses a CD8 hinge. Said passage does not disclose use of a "polypeptide spacer" other than CD8 hinge and is restricted to a disclosure of the particular construct referred to in said Figure. Claim 32

is not restricted to a nucleic acid encoding the construct disclosed in Figure 1 and encompasses use of a polypeptide spacer other than CD8 hinge and is therefore broader in scope than the actual disclosure of the specification.

b) There is no support in the specification a originally filed for the molecules of claim 26/27. Said molecules encompass nucleic acids encoding molecules that contain a polypeptide spacer and CD8 hinge wherein there is no disclosure of such molecules in the specification as originally filed.

There is no written description of the scope of the claimed inventions in the specification as originally filed (aka the claimed inventions constitute new matter).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 11-14,24-27 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11,24-27 are indefinite in that they lack antecedent basis in claim 32. The molecule of clam 32 has a spacer between the TCR variable domain and the zeta region whilst said spacer is absent in the molecule of claim 11/24-27. For the purposes of prior art, the claims will be interpreted as containing all of the components of claim 32.

8. The previously pending prior art rejections of claims 6,9-12,15-19,22-30 are withdrawn in view of the amended claims and because claim 6 has been withdrawn from consideration.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 7-17,23-25,28,29,32,33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chung et al. in view of Sette et al.

Chung et al. teaches a nucleic acid encoding a single chain TCR alpha and beta chain joined by the linker of claim 12 (see Figure 1) wherein the construct also includes the ζ region of CD3 and wherein the variable region and ζ chain are joined by a polypeptide spacer (see Figure 1 wherein CB would constitute a linker and see Materials and Methods section, pages 12654-12655). Chung et al. teach expression vectors encoding nucleic acids comprising a leader sequence and said TCR, and T cells containing said vectors and methods of making the aformentioned (see Materials and Methods wherein BW is a T cell line and Figure 1). Human CD3 ζ region is well known in the art. Chung et al. does not teach use of a nonhuman TCR which is HLA A2 restricted. Chung et al. discloses that the TCR can be derived from known T cells and that said chimeric TCR can be used for diagnostic and therapeutic purposes (see page 12658, first column). Sette et al. disclose the use of HLA A2 transgenic mice that produce T cells with nonhuman TCR that are HLA A2 restricted (see page 5588, second column). Said system has the advantage that T cells can be produced by immunizing mice using methods not acceptable in humans (for example immunization of antigen with IFA used in the example, page 5587, second column). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Chung et al. teaches the claimed invention

except for use of nonhuman TCR, whilst methods of generating nonhuman TCR that were HLA A2 restricted were known in the art. One of ordinary skill in the art would have been motivated to do the aformentioned because Chung et al. discloses that their TCR can be derived from known CTL and used in diagnostic or therapeutic methods and the method of Sette et al. can be used to produce T cells using effective immunization methods not acceptable in humans.

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chung et al. in view of Sette et al. as applied to claims 7-19,23,28,29,32,33 above, and further in view of Disis et al.

The previous rejection renders obvious the claimed invention except wherein the tumor associated antigen is Her2/neu. Chung et al. teaches that the recombinant TCR can be used for therapeutic or diagnostic purposes. Disis et al. teach that HER-2/neu is a cancer cell antigen recognized by T cells. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because the previous rejection renders obvious the claimed invention except wherein the tumor associated antigen is Her2/neu, whilst Chung et al. teaches that the recombinant TCR can be used for therapeutic or diagnostic purposes and Disis et al. teach that HER-2/neu is a cancer cell antigen recognized by T cells.

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644